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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,717	10/22/2003	Jonathan S. Stinson	10527-501001	9775

26161 7590 04/26/2007
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EXAMINER

MORILLO, JANEL COMBS

ART UNIT	PAPER NUMBER
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1742

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,717

Applicant(s)

STINSON, JONATHAN S.

Examiner

Janelle Combs-Morillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Notice of Allowance mailed 1/12/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-27,29-33,35,36,41,44-47 and 49-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 11-27, 29, 32, 33, 35, 36, 41, 44, 49-59 is/are rejected.
- 7) ☒ Claim(s) 5-9,30,31 and 45-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.
2. Prosecution on the merits of this application is reopened on claims considered unpatentable for the reasons indicated below:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 4, 11-27, 29, 32, 33, 35, 36, 41, 44, 49-59 are rejected under 35 U.S.C. 103(a) as being obvious over Craig et al (US 2003/0018380).

The applied reference has a common inventor with the instant application. Based upon the earlier publication date of the reference, it constitutes prior art under 35 U.S.C. 102(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Craig teaches a metal alloy comprising (in wt%): about 11-18% Cr, about 5-12 wt% Ni, ≥ about 15% Fe, about 5-50wt% Pt, up to about 3.0% Mo (Craig at cl. 1 and 2, Table 1), as well as

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C, Mn, P, S, Cu, N, and Si (Craig at Table 1), which overlaps or touches the boundary of the presently claimed ranges (cl. 1, 3, 11-13, 27, 29, 32, 35, 36, 41, 49-51) of Cr, Pt, and 316 series stainless steel (Fe, Ni, Mo, C, Mn, P, S, Cu, N, Si- see Craig at Table 1, [0050]). Because Craig teaches an alloy that overlaps/touches the boundary of the presently claimed alloying ranges, it is held that Craig has created a prima facie case of obviousness of the presently claimed invention.

Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility.

Additionally, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages," In re Peterson, 65 USPQ2d at 1379 (CAFC 2003).

Concerning claims 4, 44, presently claimed "greater than about 55 weight percent of platinum", is held to be a close approximation of 'about 50wt% Pt' (as taught by Craig).

Concerning claims 14-21, 33, 52-59, which mention various mechanical or microstructural/chemical properties of the instant alloy, because the alloy taught by Craig overlaps or is a close approximation of the presently claimed alloy, then substantially the same properties, such as density, pitting resistance, strength, phase, etc. are expected to occur. Once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. "[T]he PTO can require an applicant to prove that

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the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)), see MPEP 2112. In re Schreiber, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed.Cir.1997).

Concerning claims 22-26, Craig teaches said alloy is suitable for implantable and/or intravascular medical devices (abstract), such as a stent, and wherein said alloy has excellent biocompatibility and high strength [0001-0004]. Though Craig does not specify said alloy is formed into a surgical instrument, balloon catheter, fixation device, etc., because Craig teaches said alloy has excellent biocompatibility and high strength [0001-0004], it would have been obvious to one of ordinary skill in the art to form other medical devices out of said Pt-Fe alloy taught by Craig (including surgical instruments, catheters, fixation device, etc.), substantially as presently claimed.

PROVISIONAL Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3, 4, 11-27, 29, 32, 33, 35, 36, 41, 44, 49-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 19-24, 33-38 of copending Application No. 10/112391.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'391 are drawn to a Pt-Fe alloy medical device (stent) with ranges of alloying elements that overlap or touch the boundary of the presently claimed ranges of Fe, Cr, Ni, Pt, Mo, C. Though the claims of US'391 do not particularly mention S, N, Si, P, or Cu, the instant claims do not require a minimum of said elements, and said elements are held to be present in trace/impurity levels for the Pt-Fe alloy of the claims of US'391.

Concerning claims 4, 44, presently claimed "greater than about 55 weight percent of platinum", is held to be a close approximation of 'about 50wt% Pt' (as taught by cl. 1 of US'391).

Concerning claims 14-21, 33, 52-59, which mention various mechanical or microstructural/chemical properties of the instant alloy, because the alloy taught by the claims of US'391 overlaps or is a close approximation of the presently claimed alloy, then substantially the same properties, such as density, pitting resistance, strength, phase, etc. are expected to occur.

Concerning claims 22-26, the claims of US'391 teaches said alloy is suitable for medical device such as a stent (cl. 1, 4). Though the claims of US'391 does not specify said alloy is

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formed into a surgical instrument, balloon catheter, fixation device, etc., because the claims of US'391 teaches said alloy has biocompatibility suitable for forming into a stent, it would have been obvious to one of ordinary skill in the art to form other medical devices out of said Pt-Fe alloy taught by the claims of US'391 (including surgical instruments, catheters, fixation device, etc.), substantially as presently claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

7. Claims 5-9, 30, 31, 45-47 are allowable over the prior art of record.
8. Claims 5-9, 30, 31, 45-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest prior art of Craig (2003/0018380) does not teach or suggest an alloy composition comprising 'greater than about 60wt% Pt' and a 300 series stainless steel, substantially as presently claimed.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCM

April 23, 2007


ROY KING
SUPERVISORY PATENT EXAMINER
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